APR 12 2002

K020817

Summary of Safety and Effectiveness
Liquichek™ Urine Chemistry Control

1.0 Submitter

Bio-Rad Laboratories
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Contact Person

Maria Zeballos
Regulatory Affairs Specialist
Telephone: (949) 598-1367

Date of Summary Preparation

March 11, 2002

2.0 Device Identification

Product Trade Name:	Liquichek™ Urine Chemistry Control
Common Name:	Multi-Analyte Controls, (Assayed and unassayed)
Classifications:	Class I
Product Code:	JJY
Regulation Number:	21 CFR 862.1660

3.0 Device to Which Substantial Equivalence is Claimed

Liquichek™ Urine Chemistry Control
Bio-Rad Laboratories
Irvine, California

Docket Number: K971954

4.0 Description of Device

Liquichek™ Urine Chemistry Control is prepared from human urine with added constituents of human and animal origin, pure chemicals, preservatives and stabilizers. The control is provided in liquid form for convenience.

5.0 Statement of Intended Use

Liquichek™ Urine Chemistry Control is intended for use as an assayed quality control urine to monitor the precision of laboratory procedures listed in the package insert.

6.0 Comparison of the new device with the Predicate Device

Liquichek™ Urine Chemistry Control claims substantial equivalence to the Liquichek™ Urine Chemistry Control levels currently in commercial distribution (K971954). The new Liquichek™ Urine Chemistry Control contains Cortisol and the current product does not.

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Bio-Rad Liquichek™ Urine Chemistry Control (New Device)	Bio-Rad Liquichek™ Urine Chemistry Control (Predicate Device)
	Similarities	
Intended Use	Liquichek™ Urine Chemistry Control is intended for use as assayed quality control urine to monitor the precision of laboratory testing procedures for analytes listed in the package insert.	Liquichek™ Urine Chemistry Control is intended for use as assayed quality control urine to monitor the precision of laboratory testing procedures for analytes listed in the package insert.
Form	Liquid	Liquid
Matrix	Human urine based	Human urine based
Storage (Unopened)	2 to 8°C Until expiration date	2 to 8°C Until expiration date
Open Vial Claim	30 days at 2-8°C	30 days at 2-8°C
	Differences	
Analytes	Contains: Amylase, Calcium, Chloride, Cortisol, Creatinine, Glucose, Magnesium, Microalbumin, Osmolality, pH, Phosphorus, Potassium, Pregnancy, Protein- Total, Sodium, Specific Gravity, Urea, Urea Nitrogen, Uric Acid.	Contains: Amylase, Calcium, Chloride, Creatinine, Glucose, Magnesium, Microalbumin, Osmolality, pH, Phosphorus, Potassium, Pregnancy, Protein- Total, Sodium, Specific Gravity, Urea, Urea Nitrogen, Uric Acid. Does not Contain: Cortisol

7.0 Summary of Performance Data

Stability studies have been performed to determine the open vial stability and shelf life for the Liquichek™ Urine Chemistry Control. Product claims are as follows:

7.1 Open vial: Once the control material is opened, all analytes will be stable for 30 days when stored tightly capped at 2-8°C.

7.2 Shelf Life: One year and six months when stored at 2-8 °C.

Real time studies will be ongoing to support the shelf life of this product.
All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Elizabeth Platt
Regulatory Affairs/Quality Assurance Manager
Bio-Rad Laboratories, QSD
9500 Jeronimo Road
Irvine, CA 92618-2017

APR 1 2 2002

Re: k020817
Trade/Device Name: Liquichek™ Urine Chemistry Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I reserved
Product Code: JJY
Dated: March 11, 2002
Received: March 13, 2002

Dear Ms. Platt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K020817

Device Name: **Liquichek™ Urine Chemistry Control**

Indications for Use:

Liquichek™ Urine Chemistry Control is intended as an assayed quality control urine to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

Sean Logan

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020817

(PLEASE DO NOT WRITE BELOW THE LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ✓ or Over-the Counter use _____